REMARKS

In the Office Action dated April 30, 2008, claims 7-12 were rejected under 35 U.S.C. §112, second paragraph as being indefinite because the Examiner stated in claim 7, the positions of the markers are defined with respect to a non-claimed element (the implant), and claim 12 is directed to defining an unclaimed element (the implant). In response, independent claim 7 has been amended to include the implant as a claimed element. All claims of the application are therefore submitted to be in full compliance with all provisions of Section 112, second paragraph.

Claims 1-12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lee et al in view of Krause et al. This rejection is respectfully traversed for the following reasons.

As argued in Applicants' previous response, the method and apparatus disclosed and claimed in the present application make use of a plurality of x-ray detectable markers that are located in an anatomical environment of an implanted medical implant, with the markers being spatially separated from the medical implant. The medical implant itself has x-ray detectable points thereon that are different from the aforementioned markers.

The method and apparatus are for the purpose of detecting position changes of the implant, and this is accomplished by obtaining first and second 2D x-ray exposures respectively from first and second different projection directions of the region of the patient containing the implant. The exposures are respectively obtained at temporally separated times, such that a positional change of the implant in the environment may have occurred. The markers and points will have respective distributions in the two x-ray exposures and, if movement of the implant has occurred

in the environment between the exposures, these distributions will be different in the first and second exposures. From the first and second distributions in the respective exposures, a probability is automatically calculated that the first and second distributions represent the same three-dimensional distribution of the markers and the points. From this calculated degree of probability, it is determined whether a positional change of the implant in the environment has occurred.

The Examiner cited the Lee et al reference as, according to the Examiner, providing a teaching to use x-ray detectable markers both on an implant and on a bone, for the purpose of allowing an assessment to be made of the impact of the implant on the health of the bone structure.

More precisely, the Lee et al reference discloses a composition or a device that is suitable for orthopedic or dental implantation into bone. A molecule known as Tartrate-resistant acid phosphatase (TRAP) is known to be an indicator as to whether metabolic activity is occurring related to new bone growth. As explained in paragraph [0016] of the Lee et al reference, a bone implant or a bone graft can be dipped in a sterile solution of TRAP in the operating theater prior to implantation. As explained in paragraph [0017] the TRAP-induced stimulation of osteoclast recruitment results in enhanced bonding of the graft or prosthesis to the patient's bone, so that recovery time from the operation is reduced and the life of the implant is lengthened.

Therefore the Lee et al reference has nothing whatsoever to do with monitoring a change or shift in position of a medical implant. Moreover, although the Lee et al reference mentions applying a TRAP coating to either a medical implant or a bone graft, in this context the implant and graft, even though the graft is composed

of bone tissue, are essentially treated as the same item. There is no teaching of adding any type of marker to the actual living bone to which the implant or the graft is attached.

The one and only mention of any type of x-ray examination in the entirety of the Lee et al reference is in paragraph [0059], noted by the Examiner. This paragraph includes the sentence that "osteointegration is judged in individual animals in time intervals of 1–12 months after surgery by x-ray imaging to evaluate degree of radiolucency, and hence gap between metal and bone, and by retrieval, sectioning and microscopy of the metal/bone interface of the implant." Again, this statement makes no mention whatsoever of markers or x-ray detectable points being located on the implant itself as well as in the environment of the implant. This is because, as noted above, movement of the implant relative to the environment of the implant is of no interest whatsoever in the Lee et al reference. There is not even a clear explanation of how the "gap" is identified by the "radiolucency."

The Examiner has proposed combining the teachings of Lee et al reference with the teachings of the previously-cited Krause et al reference. Applicants provided extensive remarks concerning the teachings of the Krause et al reference in Applicants' previous response, and those comments are still valid, and need not be repeated herein. The Examiner is proposing modifying the fixation device used in the Krause et al reference in accordance with the teachings of Lee et al. Even if the fixation device is considered as the equivalent of an "implant," although it is not actually implanted in the body of a patient, the fixation device is an *external* device and therefore the teachings relating to TRAP, which relate exclusively to new bone

growth promotion, are not in anyway related to the external fixation device disclosed in the Krause et al reference.

Applicants' comments concerning the model generation disclosed in Krause et al have been previously presented and, based on those comment, Applicants do not agree with the Examiner's characterizations of the teachings of the Krause et al reference. Even if the teachings relating to model generation in the Krause et al reference noted by the Examiner are accepted, however, there is no interface whatsoever between those teachings and the use of TRAP in the Lee et al reference, and there certainly is no obvious use whatsoever of the use of TRAP, or the monitoring of TRAP-induced bone growth, with regard to detecting positional changes of an implant with respect to the environment of the implant, as disclosed and claimed in the present application.

In fact, the teachings of the Lee et al reference are so completely remote from and unrelated to the teachings of the Krause et al reference (as well as the content of the claims of the present application), that if a person of ordinary skill in the field of monitoring positional changes of an implanted implant had the insight to make use of anything in the Lee et al reference for the purpose of assessing such a positional change, that would be an insight supporting patentability, rather than a reason for precluding patentability under the provisions of 35 U.S.C. §103(a).

In fact, Applicants submit that the teachings of the Krause et al reference and the Lee et al reference are mutually incompatible. The fixation device, being an external device, is intended only for temporary use and at some point will be removed after immobilization produced by the fixation device is no longer necessary. It would be counterproductive if any type of bone growth promotion with regard to

this removable device were intended, and therefore there is no reason whatsoever to coat any portion of the fixation device with a TRAP-inducing coating, and therefore there is no reason whatsoever to undertake any monitoring of bone growth induced by such a TRAP coating in the environment of the "implantation" of the fixation device. If such bone growth were promoted and did occur, this would make removal of the fixation device even more difficult, and would thus be counterproductive and, if anything, would serve to make a positional change of the fixation device with regard to the bone even less likely, due to the TRAP-promoted bone growth.

The entire concept of the Lee et al reference, therefore, is that bone growth will be promoted with regard to an implant or a graft, thereby, overtime, making any positional change between the implant and the graft increasingly less likely to occur. It is assumed that if the bone growth induced by the TRAP coating occurs, positional changes will *not* occur, and therefore the necessity of undertaking any type of monitoring as disclosed and claimed in the present application is opposite to the intended purpose of the teachings of the Lee et al reference.

The respective dependent claims of the present application add further method steps or further structure to the non-obvious combinations of the independent claims. No claim of the application, therefore, would have been obvious to a person of ordinary skill in the field of detecting positional changes of a medical implant with respect to its environment, under the provisions of 35 U.S.C. §103(a), based on the teachings of Lee et al and Krause et al.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,

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